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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,953	02/09/2001	Manikkam Suthanthiran	955-3P/CON	1712

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/780,953

Applicant(s)

SUTHANTHIRAN ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-20, 26, 28, 29 and 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-25, 27, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. The response filed March 18, 2003 (Paper No. 11) is acknowledged.
2. Claims 1-35 are pending. Claims 1-20 and 32-35, drawn to non-elected inventions, are withdrawn from consideration. Claims 26, 28 and 29 do not appear to be readable on the elected species and are withdrawn from consideration.
3. Claims 21-25, 27, 30 and 31 are examined on the merits.
4. The declarations filed under 37 CFR 1.131 and 1.132 are acknowledged.

#### ***Claim Rejections Maintained:***

5. The rejection of claims 21-23 and 30 under 35 U.S.C. 103(a) as being unpatentable over Hutchinson (Hutchinson, Rev. in Immunogenetics, 1: 323-333, 1999) is maintained for the reasons of record. The declaration filed under 37 CFR 1.131 is insufficient to establish that the invention was made before the publication date of Hutchinson, because only one of the inventors signed the declaration. MPEP 715.04 requires that all inventors sign a declaration filed under 37 CFR 1.131.

Applicant further argues that the rejection should be withdrawn because Hutchinson fails to render obvious the claimed compositions. Applicant asserts that Hutchinson fails to show that

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high levels of TGF-beta 1 is a causative agent in nephrotoxicity and rejection of transplants.

This argument is unpersuasive, because Hutchinson generally teaches that high levels of TGF-beta 1 are associated with a negative outcome in transplant cases, and this implies that those transplants that do not have a negative outcome do not have high levels of TGF-beta 1. Thus, it would appear that the prior art suggests that reduction of TGF-beta 1 would be beneficial for transplant patients.

6. The rejection of claims 21-23 and 31 under 35 U.S.C. 103(a) as being unpatentable over Ader (Ader, Curr. Opin Nephrol. Hypertens., 7: 539-545, 1998) in view of Hutchison (supra) is maintained for the reasons of record.

As discussed above, the declaration filed under 37 CFR 1.131 is insufficient to remove Hutchison as prior art. Therefore, the rejection is maintained.

Ader teaches that FK-506 causes nephrotoxicity in transplant patients. As Hutchinson teaches that nephrotoxicity is probably mediated by TGF beta1, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a composition that comprised an anti-TGF beta1 antibody and an immunosuppressive agent such as FK-506.

7. The rejection of claims 21-25, 27 and 30 under 35 U.S.C. 103(a) as being unpatentable over Novak (Novak, Nature Medicine, 5(4): 382, 1999, April) in view of Ohmori (Experimental Cell Research, 245: 350-359, 1998) is maintained for the reasons of record.

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The declaration filed under 37 CFR 1.131 fails to remove Novak as prior art. Therefore, the rejection is maintained.

Novak teaches that transplant patients receiving immunosuppressants (cyclosporine) are more susceptible to cancer, and teaches that cyclosporin actually promotes tumor progression directly, and that the mechanism is mediated by TGF beta. Ohmori teaches the use of anti-TGF antibodies in the treatment of cancer. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a composition that comprises an anti-TGF beta1 antibody and an immunosuppressive agent such as cyclosporine.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892.

Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
June 28, 2003

  
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